

What nobody told you about femur fractures

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Abstract

Background: This paper intends to correlate data obtained from different orthopedic surgical teams and literature on faulty instrumentation during femoral fracture treatment with intramedullary nailing.

Objectives: 1) To define technical problems arising during surgical procedures to treat femoral fractures; 2) to compare different centers and problems; 3) to analyze possible ways to find a solution.

Methods: 1) A retrospective, descriptive, observational study on clinical records and radiologic files was performed; 2) an on-line survey was sent to orthopedic surgeons; 3) a query was sent to ANMAT, IRAM, and Ministerios de Salud de la Ciudad Autónoma de Buenos Aires y de la Nación.

Results: 1) 31 intramedullary femoral nailing procedures were performed from January 2008 to August 2013. Eighteen cases of surgical tool deficiencies in 14 patients. More frequent problems were related to drill bits and guide wires; 2) 270 forms were filled up, from 19 provinces of Argentina, and from Colombia, Ecuador, Italy, Australia and Bolivia. We received answers from 180 private institutions and 90 public hospitals; 3) there are four possible ways to reach a solution: ANMAT with its Programa de Tecnovigilancia, IRAM for non-fulfillment of ISO 9001 rules, Ministerios de Salud for nonfulfillment of resolution 255 and Ley Básica de Salud N° 153, art. 12, items k and l, and AAOT Implants Subcommittee.

Conclusions: A clear-cut difference was established between public and private centers; however, the working place only defined the prevalence of technical problems, but problems themselves were the same. There are legal and administrative tools to deal with these problems.

Key words: Femur; fracture; complications; surgical tools; nail; claim.

Level of Evidence: IV

LO QUE NO TE CONTARON DE LAS FRACTURAS DE FÉMUR

Resumen

Se relaciona la bibliografía con la experiencia de nuestros cirujanos frente a un instrumental defectuoso en el tratamiento de fracturas de fémur con osteosíntesis endomedulares.

Objetivos: 1) Enumerar inconvenientes técnicos que se presentan en las cirugías de fémur, 2) comparar diferentes centros y problemas afrontados, 3) estimar los canales de reclamo.

Materiales y Métodos: 1) Estudio retrospectivo, de observación, descriptivo sobre historias clínicas y archivo radiológico, 2) encuesta en línea enviada a traumatólogos generales, 3) consulta con la ANMAT, el IRAM, los Ministerios de Salud de la Ciudad Autónoma de Buenos Aires y de la Nación.

Conflict of interests: The authors have reported none.

Resultados: 1) 31 pacientes con fracturas de fémur tratados con osteosíntesis endomedulares entre enero de 2008 y agosto de 2013. Dieciocho casos de fallas o defectos del instrumental de colocación en 14 pacientes. Los problemas más frecuentes fueron las guías y las mechas, 2) 270 respuestas, 19 provincias argentinas, respuestas de Colombia, Ecuador, Italia, Australia y Bolivia. Se obtuvieron 180 respuestas de Centros privados y 90 de Centros públicos, 3) cuatro vías de reclamo: ANMAT bajo el programa de Tecnovigilancia, IRAM por el incumplimiento de las Normas ISO 9001, Ministerio de Salud por incumplimiento de la resolución 255 y la Ley Básica de Salud N.º 153, art. 12 (ítems k y l) y AAOT, en la subcomisión de Implantes.

Conclusión: Queda explícita la diferencia entre Centros públicos y privados; sin embargo, el medio laboral solo definió la prevalencia de inconvenientes técnicos, pero los inconvenientes fueron los mismos. Existen formas para denunciar y enfrentar esta problemática.

Palabras clave: Fémur; fracturas; complicaciones; instrumental; clavos; reclamo.

Nivel de Evidencia: IV

Introduction

Technological advances and the use of new materials in Orthopedics, plus the development of new surgical techniques that tend to preserve soft tissues made complexity, sophistication and costs of implants and insertion instruments increase. Nowadays, in our country, there is a gap between public and private health systems regarding access to and availability of the latest generation implants for the surgical treatment of fractures.

In the public health system, doctors often work with the surgical instruments that they can, not with those that they should. When doctors turn down implants or insertion instruments, waiting time for surgery increases and, paradoxically, new materials sometimes fail in meeting the required standards. On such occasions orthopedic surgeons, in front of the medical and surgical emergencies that their patients are living through, are made to use those materials received first to avoid the consequences of a greater surgical delay.

In our country, the treatment of femur fractures with intramedullary osteosynthesis is paradigmatic in this sense. It is frequent to receive defective instrumentation sets, guide wires that do not coincide with locks, stripped screws, wasted drill bits, among other problems related to the bad quality of surgical instruments, what hardens the normal development of the surgical technique. On the other hand, it is also frequent to suffer delays in the allocation of the material, what puts the surgery off and makes the surgeon use skeletal traction techniques to reduce and immobilize the fracture.

Our work comes up from a series of patients at our center with femur fractures (diaphyseal, supracondylar and subtrochanteric femur fractures). During treatment we were faced with diverse complications that triggered multiple questions—many of them related to treatment technical issues, although there were others that had to do with our work. We let the rest of the orthopedists in Argentina know our queries so as to widen the analysis of the problem and thus compare the difficulties encountered at different centers; we made it by an online questionnaire. We got answers from 270 orthopedists in the whole country and from some centers abroad.

Moreover, we believe that it is important to acknowledge that there is an articulated channel to claim when we find instrumentation sets in bad condition.

Problems

- Are there differences in insertion instruments for femur intramedullary nailing?
- Do all the Argentine centers work with similar populations and with the same tools?
- Is there a loophole when it comes to the control of the conditions and the quality of the insertion instruments for the implants that are used in femoral surgery?

Objectives

- To make a list of the drawbacks related to defective insertion instruments during the surgical treatment of femur fractures with intramedullary osteosynthesis, both at our hospital and at our population of reference.
- To compare different public and private centers in terms of the treatment of these fractures and the technical problems encountered at different centers that carry out the same procedures.
- To help the reader with guidelines about how to proceed with the drawbacks that may arise with the insertion instruments for implants.

Hypothesis

- H1: There might be complications in the surgical treatment of femur fractures with intramedullary nailing associated with defective insertion instruments.
- H2: The working place might define different degrees and types of technical drawbacks in the surgical treatment of femur fractures with intramedullary nailing.
- H3: There might be a loophole in the regulation of the conditions and the quality of the materials for implants insertion. We might be lacking in an articulated channel to claim at the time of confronting these problems.

Materials and Methods

We performed bibliographic research looking for articles that address the complications related to defective insertion

material in the treatment of femur fractures with intramedullary osteosynthesis, across databases Medline and Cochrane using key words (MESH): “surgical instrument failure”, “stripped screws”, “screw failure”, “endomedullary osteosynthesis failure”, “guides”. Moreover, we e-mailed the Asociación Argentina de Ortopedia y Traumatología requests for published studies using the same key words. We excluded articles that describe postoperative complications in the treatment of both femoral fractures and proximal femur fractures. We found 10 articles: four made reference to intraoperative complications during the treatment of femur shaft fractures with intramedullary antero-grad nailing,¹⁻⁴ five articles were all about surgical tips for the removal of failed intramedullary osteosynthesis and broken screws of intramedullary nails⁵⁻⁹ and there was only one article about the complications related to the use of blunt drill bits during intramedullary reaming.¹⁰ All the articles found were of low level of evidence; in general they were case reports (Level IV).

Following, we divide the study in three phases:

Phase 1: We carried out a retrospective, observational and descriptive study of medical histories and X-ray files at the Orthopedics Department at the institution we work at. We designed an Excel spreadsheet to enumerate the complications encountered. For the purposes of the study, we define every intraoperative complication that alter the development of the surgical technique which has been planned before the surgery and which has to do with a defective or incomplete insertion instruments set as “complication related to the insertion instruments”.

Inclusion criteria: Complete medical histories of patients operated on at our center from January 2008 to August 2013 due to femur fracture, with full availability of the surgical protocol and X-rays that document the problems encountered during the surgery. Patients treated with intramedullary osteosynthesis.

Exclusion criteria: Incomplete or illegible medical histories, lateral and medial hip fractures, pathologic fractures, revision surgeries, peri-prosthetic fractures, femur fractures treated with plate and screws, femur non-union.

Phase 2: We carried out a transversal descriptive study looking for complications related to insertion instruments during the treatment of femur fractures, using a questionnaire designed by the experimented surgeons on the Hip and Trauma teams at the institution we work at, with 16 multiple-choice questions. Apart from the questions related to defective or incomplete insertion material sets, we included questions about preoperative reduction, preoperative waiting time and the availability of a Trauma team having experience of the treatment of these fractures (surgeons, anesthesiologists and surgical instrumentalists), because we believe these are factors that influence the surgical timing. Taking as source the e-mail database at our center, we used the app Google Drive to e-mail the questionnaire to orthopedists at national and international institutions who gave their consent.

Inclusion criteria: General orthopedists at private and public centers that agreed to answer the survey received by e-mail.

Exclusion criteria: Incomplete questionnaires or questionnaires sent in formats alternative to those designed by the authors.

Phase 3: We carried out bibliographic research and consulted specialists in diverse disciplines (medical doctors, lawyers and engineers) working for referential institutions such as the National Administration of Medicines, Food and Technology (ANMAT, by its Spanish acronym), the Argentine Institute of Rationalization of Materials (IRAM, by its Spanish acronym), the Ciudad Autónoma de Buenos Aires Health Department and the National Health Department, so as to document an articulated channel for claiming in the case of technical problems with the insertion material during the surgery.

Results

Phase 1: We included 31 patients with femur fractures operated on with intramedullary osteosynthesis from January 2008 to August 2013 that met the aforementioned inclusion criteria. They were 16 males and 15 females ranging from 14 to 95 years old (57.09 on average): 16 shaft fractures, 13 subtrochanteric fractures and three supracondylar fractures; two open fractures and 29 closed fractures. Fourteen cases were treated with femur antero-grad intramedullary nailing; four, with retrograde intramedullary nailing, and 13, with femur cephalomedullary nailing. As method of preoperative reduction and immobilization we used skeletal traction in 30 patients, 2 were fixed with external fixation; nine patients (29%) suffered comorbidities: high blood pressure (3 cases), arrhythmia (2 cases), chronic cognitive impairment (2 cases), hypothyroidism (2 cases), aortic stenosis (1 case), schizophrenia (1 case), prostate cancer (1 case), CREST syndrome (1 case), epilepsy (1 case) and HIV (1 case). Preoperative waiting time in days ranged from 4 to 70 (average 18.78). We found 18 cases of failures or defects in the insertion instruments, documented in the surgical protocols of 15 patients (48.38%): lack of options of locking screws (4 cases: 12.9%); defective insertion frames (3 cases: 9.67%); scratched screws (3 cases: 9.67%); drill bit rupture (1 case: 3.22%); guide wire that did not coincide with the proximal lock (1 case: 3.22%); lack of screw depth gauge (1 case: 3.22%); lack of options of intramedullary nails (2 cases: 6.45%); blunt drill bit (1 case: 3.22%); lack of screw driver (1 case: 3.22%); osteosynthesis failure (1 case: 3.22%) (Table 1).

Phase 2: We received 270 questionnaires—223 were sent by orthopedists working in Argentina who met the inclusion criteria. They represented 19 of the 23 Argentine provinces. We got 101 answers from private centers (38 from orthopedists working at private center in the Ciudad Autónoma de Buenos Aires, and 63 from orthopedists working at private center in the provinces), and 122 answers from public centers (25 from orthopedists working at public centers in the Ciudad Autónoma de Buenos

Aires, and 97 from orthopedists working at public centers in the provinces). We also got 10 questionnaires from Colombia, Ecuador, Italy, Australia and Bolivia, which were not included in the statistical analysis because they were a small group of answers coming from very different regions and representing very different circumstances. We present the survey and the analysis of the results (Table 2). The survey was made up of 16 questions divided into two groups: preoperative time and intraoperative time. Following we summarize the most significant results given by the questionnaires and, in Table 2, we detail all the answers classified in six groups: Public institutions, private institutions, public institutions in the Ciudad Autónoma de Buenos Aires, private institutions in the Ciudad Autónoma de Buenos Aires, public institutions in the provinces, and private institutions in the provinces.

Question 1: What type of preoperative reduction do you use?

Skeletal traction is the preoperative reduction method most frequently acknowledged both at public and private centers in the whole country. At public centers it is chosen more often than at private centers—more than 95% of the surveyed doctors. *Public institutions* (n=122): 116 acknowledged skeletal traction (95.08%). *Private institutions* (n=101): 86 acknowledged skeletal traction (86.86%). Only three surveyed professionals answered they did not reduce the fracture preoperatively, the three of them at private centers.

Questions 2: Who controls the preoperative reduction?

The control of the fracture reduction in charge of the resident under the Trauma team's supervision was the main answer at both public and private centers in the whole country. *Public institutions* (n=122): 66 orthopedists answered "The resident under the Trauma team's supervision" (54.1%); *Private institutions* (n=101): 43 orthopedists answered "The resident under the Trauma team's supervision" (42.47%). However, the participation of the experienced doctor of the team was more frequent at private centers, and the highest figures came from private institutions in the provinces. *Private institutions in the provinces* (n=63): 24 orthopedists reported control by "the experienced doctor of the team" (38.1%). Least participation of the experienced doctor in the team was at public institutions in the Ciudad Autónoma de Buenos Aires. *Public institutions in the Ciudad Autónoma de Buenos Aires* (n=25): three orthopedists reported control by "the experienced doctor of the team" (12%).

Question 3: Did you encounter difficulties in the surgical treatment of these fractures due to lack of adequate preoperative reduction?

The answer "Many times" was much more frequent at public institutions than at private institutions. *Public institutions* (n = 122): 24 orthopedists answered that "Many times" they encountered problems with reduction (19.67%). *Private institutions* (n = 101): 10 orthopedists answered that "Many times" the encountered problems

with reduction (9.9%). The highest percentage was at public institutions in the Ciudad Autónoma de Buenos Aires. *Public institutions in the Ciudad Autónoma de Buenos Aires* (n=25): 10 orthopedists encountered problems with reduction "Many times" (40%).

Question 4: What is your surgical waiting time in the treatment of these fractures?

Seventy three percent of the surveyed doctors working at private institutions answered that they had a surgical waiting time shorter than one week vs. 11% of those working at public hospitals. *Private institutions* (n = 101): 74 reported a surgical waiting time shorter than one week (73.26%). *Public institutions* (n = 122): 14 reported a surgical waiting time shorter than one week (11.46%). Only 6.18% of the professionals working at public hospitals in the provinces, and 32% of those working at public hospitals in the Ciudad Autónoma de Buenos Aires answered that they operated on their patients within the first week. *Public institutions in the provinces* (n = 97): six reported a surgical waiting time shorter than one week (6.18%). *Public institutions in the Ciudad Autónoma de Buenos Aires* (n = 25): eight reported a surgical waiting time shorter than one week (32%).

Question 5: Is there a Trauma team that carries out these surgeries?

In general, the answer "Yes" was given by more than 40% of professionals at both private and public institutions. *Private institutions* (n = 101): 63 answered that they had a Trauma team (62.37%). *Public institutions* (n = 122): 52 answered that they had a Trauma team (42.62%). Not having a Trauma team to carry out these surgeries as an answer was more frequent among professionals at public institutions in the provinces. *Public institutions in the provinces* (n = 97): 58 answered that they did not have a Trauma team (59.79%).

Question 6: Who operates on these fractures at the institution you work at?

Sixty three point three percent of orthopedists at private centers reported that it is the Trauma team that operates on these fractures vs. 32.78% of orthopedists at public hospitals. *Private institutions* (n = 101): 64 surveyed doctors answered "The Trauma team"; *Public institutions* (n = 122): 40 professionals answered "The Trauma team". The answer more frequently found among professionals at public centers was "The resident under staff doctors' supervision". *Public institutions in the Ciudad Autónoma de Buenos Aires* (n = 25): 11 surveyed doctors answered: "The resident under staff doctors' supervision". *Public institutions in the provinces* (n = 97): 45 surveyed doctors answered: "The resident under staff doctors' supervision".

Question 7: Do you always work with the same surgical instrumentalist?

The answer more frequently given by professionals at all centers was that they did not always work with the same surgical instrumentalist. The number of "No" answers was higher among orthopedists at public hospitals vs. private centers. *Public institutions* (n = 122): 99 ortho-

Table 1. Cases Spreadsheet

	Sex	Age	Comorbidities	Fracture	Open	Immobilization	Surgical waiting time (days)	Surgery	Intraoperative problems
1	M	82		ST	No	ST	4	G	
2	F	95		ST	No	No	6	PFN	
3	M	32		D	No	ST	5	IMN	
4	F	22		D	No	ST	8	IMN	Defective insertion frame. Lack of options of locking screws
5	F	63	High blood pressure Left branch bundle block	ST	No	ST	8	LG	
6	F	72		D	No	ST	10	IMN	Defective insertion frame
7	F	89		ST	No	ST	11	G	
8	M	62		D	No	ST	11	LG	
9	F	66	Hypothyroidism	ST	No	ST	12	G	Blunt drill bit
10	M	70	Advanced prostate cancer	D	No	ST	13	IMN	Lack of options of nails diameters
11	F	67	CREST	ST	No	ST	14	G	Stripped screws
12	M	42		ST	No	ST	15	G	Lack of options in nail lengths
13	M	88		D	No	ST	15	RN	
14	F	88		SC	No	ST	15	RN	Lack of options of locking screws
15	F	91		ST	No	ST	17	G	
16	M	28		D	No	ST	18	IMN	Stripped screws
17	M	22		D	Yes	ST	18	IMN	
18	M	33	HIV, Epilepsy	SC	No	ST	19	IMN	
19	M	24		D	No	ST	19	IMN	Lack of options of locking screws
20	M	60		ST	No	ST	20	LG	
21	F	74	High blood pressure	ST	No	ST	20	LG	Guide wire that does not coincide with proximal lock. Failed screwdrivers
22	F	82	High blood pressure, Aortic stenosis, Hypothyroidism	ST	No	ST	26	G	
23	M	30		D	Yes	ST	26	RN	
24	M	14	Chronic cognitive impairment	ST	No	ST	29	IMN	Stripped screws
25	F	82		D	No	ST	31	RN	
26	M	33		D	No	EF	32	IMN	
27	M	19		D	No	ST, EF	34	IMN	Drill bit rupture, Nail bending
28	F	78	Schizophrenia Arrhythmia Chronic cognitive impairment	ST	No	ST	70	G	
29	F	46		D	No	ST		IMN	Defective insertion frame
30	F	53		D	No	ST		IMN	
31	F	63		D	No	ST		IMN	Lack of options of locking screws

F = Female; M = Male; D = Diaphyseal Fracture; ST = Subtrochanteric Fracture; SC = Supracondylar Fracture; ST = Skeletal traction; EF = External Fixation; G = Gamma Nailing; LG = Long Gamma Nailing; PFN = Proximal Femoral Nailing; IMN = Intramedullary Nailing; RN = Retrograde Nailing.

pedists answered “No” (81.14%) *Private institutions* (n = 101): 65 orthopedists answered “No” (64.35%).

Question 8: Has it happened to you that you did not have a technician to work with during the surgery?

The answer more frequently given by professionals at private centers was: “Few times” vs. professionals at public centers, where 58% answered that they “Many times” suffered the lack of a technician during the surgery. This is the tendency while analyzing public and private centers in the Ciudad Autónoma de Buenos Aires and in the provinces. *Public institutions* (n = 122): 71 answered “Many times” (58.19%). *Private institutions* (n = 101): 53 answered “Few times” (52.47%).

Question 9: Do you think that this can influence the development of the surgery?

The answer “Yes” was the most frequent one among orthopedists at all centers in the country. *Public institutions* (n = 122): 92 orthopedists answered “Yes” (75.40%), *Private institutions* (n = 101): 83 orthopedists answered “Yes” (82.17%).

Question 10: Do you always work with the same anesthesiologist?

The answer “No” was the one most frequently given among orthopedists at all centers in the country, reaching about 80% everywhere. *Private institutions* (n = 101): 81 orthopedists answered “No” (80.19%). *Public institutions* (n = 122): 102 orthopedists answered “No” (83.6%).

Question 11: Do you work with an X-ray technician in the surgery or it is a resident the one who does this job?

In general, the answer “There is an X-ray technician” was the most frequent one among orthopedists at all centers in the country. *Private institutions* (n = 101): 84 orthopedists answered “There is an X-ray technician” (83.16%), *Public institutions* (n = 122): 95 orthopedists answered “There is an X-ray technician” (77.86%). However, the answer “There is no an X-ray technician, it is the resident who does this job” was more frequent at public centers in the Ciudad Autónoma de Buenos Aires (six orthopedists; 24% of the surveyed doctors).

Question 12: When do you check the surgical material?

In the Ciudad Autónoma de Buenos Aires, orthopedists at public hospitals answered mainly that they checked the surgical material before sterilization, vs. orthopedists at private centers who more frequently reported checking it at the time of the setting of the instruments table. *Public institutions in the Ciudad Autónoma de Buenos Aires* (n = 25): 14 orthopedists answered “Before sterilization” (56%). *Private institutions in the Ciudad Autónoma de Buenos Aires* (n = 38): 19 orthopedists answered “During the setting of the instruments table” (50%). This difference did not show among orthopedists in the provinces, where both those working at public centers and those working at private centers answered mostly that they checked the surgery material preferably before sterilization.

Question 13: Have you experienced missing parts or failures in insertion instrument sets?

The answer “Yes” was the most frequent one at all centers in the country. The answer “Many times” prevailed among orthopedists at public centers (>50% of the surveyed doctors). At private centers, the most frequent answer was “Few times”, with figures around 60%. Only nine orthopedists among all the surveyed doctors (n=223) answered “Never”. *Private institutions* (n = 101): 60 orthopedists answered “Few times” (59.4%), *Public institutions* (n = 122): 65 answered “Many times” (53.27%).

Question 14: In the case your answer to Question 13 was “Yes”, specify,

The problems most frequently reported at all the centers in the country were related to guide wires and drill bits (Table 3).

Question 15: Have you experienced missing parts or failures in the implants you were about to insert?

The answer “No” was the most frequent one at all centers in the country. Among orthopedists at private and public centers the prevailing answer was “Few times”. If we draw differences between those at institutions in the Ciudad Autónoma de Buenos Aires and those at institutions in the provinces, orthopedists at public hospitals in the Ciudad Autónoma de Buenos Aires were the exception because 56% of them answered: “Many times”. *Public institutions* (n = 122): 75 orthopedists answered “Few times” (61.47%). *Private institutions* (n = 101): 64 orthopedists answered “Few times” (63.36%), *Public institutions in the Ciudad Autónoma de Buenos Aires* (n = 25): 14 orthopedists answered “Many times” (56%).

Question 16: In the case your answer to Question 15 was “Yes”, specify,

The most prevailing answer at all centers in the country was “Lack of options of nails and screws” (Table 4).

Phase 3: While doing research on regulations and quality control of surgical materials, and emphasizing instrument sets for implants insertion, we found that the ANMAT, a decentralized organization that belongs to the National Public Administration and was created by the decree 1490/92 to reach the main objectives in matters of health policies that were established by the National Executive Power, does not include the control of this type of re-usable surgical instruments within its field of action. There is the Law 16,463, the decree 9763/64, Direction of Medical Technology, which rules fabrication control. However, the ANMAT includes a Technovigilance Program that receives reports on failures of surgical material by filling in a form with the following info: (<http://www.anmat.gov.ar/farmaco/tecnovigilancia.asp>).

It is worth mentioning the Health Basic Law N° 153 sanctioned by the Legislature of the Ciudad Autónoma de Buenos Aires on February 25th, 1999, which in its article N° 12 alludes to the functions in charge of the enforcement authorities and includes within its field of action the regulation and control of health technology, and the

Table 2. Results

1. Type of reduction						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Skeletal traction (ST)	86 (86.86%)	116 (95.08%)	33 (86.84%)	53 (84.12%)	24 (96%)	92 (94.84%)
No ST	14 (13.86%)	6 (4.92%)	5 (13.15%)	10 (15.87%)	1 (4%)	5 (5.15%)
No fracture reduction	3 (2.97%)	0	1 (2.63%)	2 (3.17%)	0	0
2. Who controls the reduction?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
The resident under the Trauma team's supervision	43 (42.47%)	66 (54.1%)	18 (47.36%)	25 (39.68%)	17 (68%)	49 (50.51%)
Only the resident	7 (6.93)	8 (6.55%)	5 (13.16%)	2 (3.17%)	5 (20%)	3 (3.1%)
The experienced doctor	35 (34.65%)	36 (29.51%)	11 (28.95%)	24 (38.1%)	3 (12%)	33 (34.02%)
Other answers (1)	16 (15.84%)	12 (9.83%)	4 (10.52%)	12 (19.04%)	0	12 (12.37%)
3. Did you experience difficulties in the surgical treatment of this fracture due to inadequate preoperative reduction?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Few times	10 (9,9%)	33 (27,04%)	21 (55,26%)	27 (42,85%)	2 (8%)	22 (22,68%)
Some times	43 (42,57%)	65 (53,27%)	16 (42,1%)	27 (42,85%)	13 (52%)	52 (53,6%)
Many times	48 (47,52)	24 (19,67%)	1 (2,63%)	9 (14,28%)	10 (40%)	23 (23,71%)
4. Surgical waiting time						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Up to 1 week	74 (73.26%)	14 (11.47%)	30 (78.94%)	44(69.84%)	8 (32%)	6 (6.18%)
1-2 weeks	20 (19.80%)	50 (40.98%)	5 (13.15%)	15(23.8%)	5 (20%)	45 (46.39%)
2- 3 weeks	2 (1.98%)	36 (29.5%)	1 (2.63%)	1(1.58%)	8 (32%)	28(28.86%)
More than 3 weeks	3 (2.97%)	19 (15.57%)	1(2.63%)	2(3.17%)	4 (16%)	15 (15.46%)
Other answers (1)	2 (1.98%)	3 (2.45%)	1(2.63%)	1(1.58%)	0	3 (3.09%)
5. Is there a Trauma team that carries out these surgeries?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Yes	63 (62.37%)	52 (42.62%)	21 (55.26%)	42 (66.66%)	13 (52%)	39 (40.20%)
No	38 (37.62%)	70 (57.37%)	17 (44.73%)	21 (33.33%)	12 (48%)	58 (59.79%)
6. Who operates on these fractures at the institution you work at?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
The Trauma team	64 (63.36%)	40 (32.78%)	17 (44.73%)	47 (74.6%)	1 (4%)	39 (40.2%)
The resident under the Trauma team's supervision	11 (10.89%)	13 (10.65%)	5 (13.15%)	6 (9.52%)	9 (36%)	4 (4.12%)
The resident under the staff doctors' supervision	21 (20.79%)	56 (45.9%)	13 (34.21%)	8 (12.69%)	11 (44%)	45 (46.39%)
The resident under the chief of residents' supervision	0	4 (3.27%)	0	0	3 (12%)	1 (1.03%)
Other answers (1)	5 (4.95%)	9 (7.37%)	3 (7.89%)	2 (3.17%)	1 (4%)	8 (8.24%)

7. Do you always work with the same surgical instrumentalist?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Yes	36 (35.64%)	23 (18.85%)	9 (23.68%)	27 (42.85%)	7 (28%)	16 (16.49%)
No	65 (64.35%)	99 (81.14%)	29 (76.31%)	36 (57.14%)	18 (72%)	81 (83.50%)
8. Has it happened to you that there is no technician during the surgery?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Never	16 (15.84%)	5 (4.09%)	3 (7.89%)	13 (20.63%)	1 (4%)	4 (4.12%)
Few times	53 (52.47%)	46 (37.7%)	24 (63.15%)	29 (46.03%)	11 (44%)	35 (36.08%)
Many times	32 (31.68%)	71 (58.19%)	11 (28.94%)	21 (33.33%)	13 (52%)	59 (59.79%)
9. Do you think that this can influence the development of the surgery?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Yes	83 (82.17%)	92 (75.40%)	32 (84.21%)	51 (80.95%)	19 (76%)	73 (75.25%)
No	18 (17.82%)	30 (24.59%)	6 (15.78%)	12 (19.04%)	6 (24%)	24 (24.74%)
10. Do you always work with the same anesthesiologist?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Yes	20 (19.8%)	20 (16.39%)	6 (15.78%)	14 (22.22%)	3 (12%)	17 (17.52%)
No	81 (80.19%)	102 (83.6%)	32 (84.21%)	49 (77.77%)	22 (88%)	80 (82.47%)
11. Do you work with an X-ray technician in the surgery or it is a resident who does this job?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
There is an X-ray technician	84 (83.16%)	95 (77.86%)	33 (86.84%)	51 (80.95%)	17 (68%)	78 (80.41%)
There is an X-ray technician, but I prefer that the resident does this job	5 (4.95%)	10 (8.19%)	1 (2.63%)	4 (6.34%)	1 (4%)	9 (9.27%)
There is no X-ray technician, it is the resident who does this job	11 (10.89%)	11 (9.01%)	3 (7.89%)	8 (12.69%)	6 (24%)	5 (5.15%)
Other answers (1)	1 (0.99%)	6 (4.91%)	1 (2.63%)	0	1 (4%)	5 (5.15%)
12. When do you check the surgical material?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Before sterilization	50 (49.59%)	77 (63.11%)	7 (18.42%)	43 (68.25%)	14 (56%)	63 (64.94%)
During the setting of the instruments table	31 (30.69%)	23 (18.85%)	19 (50%)	12 (19.04%)	7 (28%)	16 (16.49%)
I don't check the material because I always work with the same sets	2 (1.98%)	2 (1.63%)	1 (2.63%)	1 (1.58%)	0	2 (2.06%)
Other answers (1)	18 (17.82%)	20 (16.39%)	11 (28.94%)	7 (11.11%)	4 (16%)	16 (16.49%)

13. Have you experienced missing parts or failures in surgical instruments?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Never	4 (3.96%)	5 (4.09%)	1 (2.63%)	3 (4.76%)	2 (8%)	3 (3.09%)
Few times	60 (59.4%)	50 (40.98%)	21 (55.25%)	39 (61.9%)	7 (28%)	43 (44.32%)
Many times	37 (36.63%)	65 (53.27%)	16 (42.1%)	21 (33.33%)	16 (64%)	49 (50.51%)
Always	0	2 (1.63%)	0	0	0	2 (2.06%)
14. If your answered "Yes" to Question 13, specify						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Guides	61	86	24	37	16	70
Bone impactors	21	35	10	11	5	30
Material to remove screws	37	48	16	21	11	37
Reduction clamps	37	52	11	26	12	40
Drill bits	68	80	26	42	16	64
Others	19	31	10	9	2	29
15. Have you experienced missing parts or failures in implants?						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Never	8 (7.92%)	5 (4.09%)	1 (2.63%)	7 (11.11%)	1 (4%)	4 (4.12%)
Few times	64 (63.36%)	75 (61.47%)	25 (65.78%)	39 (61.9%)	10 (40%)	65 (67.01%)
Many times	29 (28.71%)	41 (33.6%)	12 (31.57%)	17 (26.98%)	14 (56%)	27 (27.83%)
Always	0	1 (0.81%)	0	0	0	1 (1.03%)
16. If your answered "Yes" to Question 15, specify						
	Private centers (n = 101)	Public centers (n = 122)	Private centers in the Ciudad Autónoma de Buenos Aires (n = 38)	Private centers in the provinces (n = 63)	Public centers in the Ciudad Autónoma de Buenos Aires (n = 25)	Public centers in the provinces (n = 97)
Stripped or dirty nails	28	31	9	19	11	20
Lack of sizes/ options in nails or screws	86	110	35	51	23	87
Screws that lose their heads at the time of driving them	43	63	18	25	15	48
Re-used screws	31	50	10	21	15	35
Rupture of implant during insertion	7	19	3	4	4	15
Others	3	7	1	2	0	7

Table 3. Lacking items or failings in the surgical instruments set

Guide wires: 27%
 Drill bits: 27%
 Clamps: 18%
 Screws removal instruments: 18%
 Impactors: 10%

Table 4. Lacking items or failings in implants

43% Lack of options of plates, nails and screws
 22% head-less screws
 18% re-used screws
 13% scratched or dirty implants
 4% rupture of the implant during insertion

regulation and control of production, commercialization and consumption of medical/surgical consumables and dressing consumables. The Health Department issues the resolution N° 225 that alludes to the chain of distribution of medical consumables, but does not make it clear if the kind of instruments discussed in this work fall within the resolution.

Another important item to highlight is the one related to the Quality Norms described under the denomination ISO 9001, which establishes the level of quality management of the companies and their products, which, among others, are supervised by the IRAM. If someone encounters a problem with insertion materials, he or she could report the problem to this organization, which would audit the reported company and if quality norms are not met, it could remove its stamp ISO 9001. Every insertion instruments set should include a users' manual which states what circumstances the instruments should not be used under with remittance back to the manufacturer.

Lastly, we could make the report on defective insertion materials and implants to the sub-committee of the Asociación Argentina de Ortopedia y Traumatología, which has records and promotes medical report and action under these circumstances.

In summary, if we are faced with any problem related to the insertion instruments set, we can resort to four reporting alternatives: 1) the ANMAT with its Technovigilance Program, 2) the IRAM, for failure to meet the Norms ISO 9001, 3) the Health Department, for breach of resolution 255 and of Health Basic Law N° 153 (items k and l) and 4), the Asociación Argentina de Ortopedia y Traumatología implants sub-committee.

Discussion

With respect to the normal development of the surgical treatment of femur fractures with intramedullary osteosynthesis, we believe that, apart from having adequate insertion materials and implants, we have to consider preoperative circumstances that may condition the preoperative planning, such as the delay of the requested implant with the consequent increase in the surgical waiting time and, therefore, the need of adequate preoperative reduction of the fracture and immobilization of the affected limb. It is difficult to find international works describing preoperative skeletal traction as the reduction method of these fractures;¹¹ however, in our country, the answer "Yes" to the question about its use was almost unanimous, except for orthopedists working at centers where these fractures can be operated on within the first week, which occurs mostly at private centers. With respect to the control of the preoperative reduction, at private centers we verified the experienced doctors participating more in the control of tractions and, since many had intraoperative problems due to bad fracture reduction, we believe that preoperative reduction and its control are very important factors to consider for the right development of the surgery.

Surgical waiting times at public centers were clearly longer than at private centers, what would influence clearly the prognosis of femur fractures. Maybe these differences have to do with access to and availability of implants once the patient has been admitted.

Having an organized Trauma team to treat these fractures facilitates organization, experience and development of protocols to optimize the treatment of these fractures.

Among the surveyed doctors, the answer "Yes" to the question about having organized Trauma teams, as well as their participation in the treatment of this type of fractures was more frequent among orthopedists at private centers in the Ciudad Autónoma de Buenos Aires and in the provinces. On the contrary, orthopedists at public centers in the provinces showed the lowest figures for such answers and reported greater participation of residents as surgeons. It just make sense to suppose that the lack of a stable and specialized team in the management of the traumatized patient along with the resident's less experience can influence final outcomes.

Moreover, in the treatment of femur fractures we regard as relevant the experience and expertise of surgical instrumentalists and anesthesiologists, who tend not to stay at public and private hospitals. There are several works that report better outcomes when communication and interpersonal relationships among the different members of the team are optimal.^{12,13} Public centers lack in surgical technicians more frequently, what to us may come as an influence on the development of the surgery, as most of the surveyed doctors believe it to be.

The need of intraoperative images taken with a mobile C-arm to guide the reduction and the insertion of the implant highlights the importance of working with a trained radiologist at the operating theatre. Although the answer to the question about him/her was more frequently "Yes", at both public and private centers often residents do that job, due to either missing technicians or technicians' lack of experience. Ten percent of the surveyed doctors made reference to this problem.

The problem of lacking adequate insertion material was frequent in our series: 18 cases of failure of or defects in the insertion instruments set, documented in 14 patients' surgical protocols. The most frequent problems were the lack of options of locking screws, defective insertion frames and stripped screws. Coincidentally, the doctors that we surveyed reported similar problems. Only nine out of 223 orthopedists answered to "Never" have suffered problems related to insertion instruments for implants. Among orthopedists at public and private centers, although the prevalence changes, problems are of the same type and the most frequent ones have to do with defective guide wires and drill bits. The answer of having suffered this problem "Many times" was given by more than 30% of the orthopedists surveyed in each group, among whom those who work at public hospitals in the Ciudad Autónoma de Buenos Aires and the provinces present the highest percentages. With respect to the failures or the missing parts in implants, again, public

centers in the Ciudad Autónoma de Buenos Aires were the least benefitted by statistics as compared to private centers. As it happens with the insertion instruments, with implants what changed was the frequency problems arise in every group, but the problems were similar—the lack of options was the problem most frequently reported.

Inadequate instrument sets may be related to the constant change of companies that provide the material through tenders that are given to provider companies that involve a reduction of the budget and, many times, lower quality. In view of this problem, we believe that

it is important to check the surgical instruments before the surgery and, this way, be able to make the complaints in time. Orthopedists at public hospitals in the Ciudad Autónoma de Buenos Aires and those at public and private institutions in the provinces tag the surgical material as revised most times before sterilization. Here, fewer than 2% of the surveyed doctors answered that they “did not revise the material”, maybe because they work with osteosynthesis banks or always with the same company.

Lastly, regarding regulations and control of insertion instruments for implants, we found a regulatory framework with forms and resources to report and confront this problem. We should highlight especially the role of the implants sub-committee of the Asociación Argentina de Ortopedia y Traumatología and the medical report of defective sets.

Conclusions

The differences in terms of therapeutic possibilities at public and private institutions are clear-cut—in general, statistics favored private practices. This proves that, many times, in view of statistics and conclusions coming from scientific works, it is important to be analytical enough so as to assess if the design was adequate and the results are statistically significant, and also ponder if what has been shown by the international bibliography can be projected onto our population.

There is little bibliography that explains how to solve intraoperative technical problems with insertion materials in femur fractures; paradoxically enough, this is a prevailing problem at all the centers that participated in our survey.

The working place only conditioned the prevalence of the technical drawbacks, but the type of drawbacks was the same. We believe that it is important to have files for this type of complications and publish works about them, especially because they put the development of the surgery at stake.

There isn't a “loophole” in the regulation and controls of the conditions of the insertion materials for implants, and there are articulated channels to claim; with our work, we intend to enumerate them and spread them.

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